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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,783	06/27/2003	Sanjay Kumar Nigam	15670-053001 / SD2001-205	8109
41790	7590	11/16/2005	EXAMINER	
BUCHANAN INGERSOLL LLP (INCLUDING BURNS, DOANE, SWECKER & MATHIS) 12230 EL CAMINO REAL SUITE 300 SAN DIEGO, CA 92130			FORD, ALLISON M	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 11/16/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/608,783	<b>Applicant(s)</b> NIGAM ET AL.	
	<b>Examiner</b> Allison M. Ford	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a method of propagating and culturing uterine bud cells in culture, classified in class 435, subclass 1.1, for example.
- II. Claims 40-42, drawn to a method of propagating and culturing metanephric mesenchyme in culture, classified in class 435, subclass 375, for example.
- III. Claims 8-10 and 22-38, drawn to a method for stimulating branching morphogenesis in kidney cell culture, classified in class 435, subclass 384.
- IV. Claims 11-20, drawn to a method for stimulating epithelial organogenesis, classified in class 424, subclass 93.7.
- V. Claims 21 and 43-48, drawn to a method for engineering a functional mammalian kidney or renal tissue, classified in class 435, subclass 373.
- VI. Claims 39, 49-56, and 67, drawn to a constructed kidney or renal tissue, classified in class 435, subclass 325, for example.
- VII. Claims 57-61, drawn to a method of treatment involving kidney transplantation, classified in class 424, subclass 422.
- VIII. Claims 62-66, drawn to a method of treatment involving administration of pleiotrophin and/or heregulin, classified in class 424, subclass 198.1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of each of groups I-V and VII-VIII are directed to different inventive methods which are not connected in design, operation, and/or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different

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functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone. Specifically, the method of Group I requires the isolated culture of embryonic uterine bud cells, which is not performed by the other methods. The method of Group II requires the isolated culture of embryonic metanephric mesenchyme, which is not performed by the other methods. The method of Group III requires contacting mature kidney cell culture with mesenchymally-derived growth factors, which is not required by any of the other groups. The method of Group IV requires culture of mature epithelial tissues, which is not required in any of the other methods. The method of Group V requires the co-culturing of uterine bud cells and metanephric mesenchyme in a specific matrix, which is not required by any of the other methods. The method of Group VII requires a step of transplanting a kidney, which is not required by any of the other groups. The method of Group VIII requires a step of administering pleiotrophin and/or heregulin directly to a patient, which is not required by any of the other groups.

Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the engineered functional mammalian tissue can be made by a variety of cell culture methods including use of a cell scaffold and seeding appropriate cells thereon; therefore the product can be made by methods distinct from the method of invention V. The methods of Groups I-IV and VII-VIII do not create an engineered kidney or renal tissue as taught by Group V; therefore the methods are unrelated to the product.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search

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for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

Claims 6 and 47 are generic to a plurality of disclosed patentably distinct species of biocompatible matrix material comprising a) a cotton, b) a collagen, c) a polyglycolic acid; d) a cat gut suture; e) a cellulose; f) a gelatin; g) a dextran; h) a polyamide; I) a polyester; j) a polystyrene; k) a polypropylene; l) a polyacrylate; m) a polyvinyl; n) a polycarbonate; o) a polytetrafluorethylene; p) a nitrocellulose compound; q) a Matrigel. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

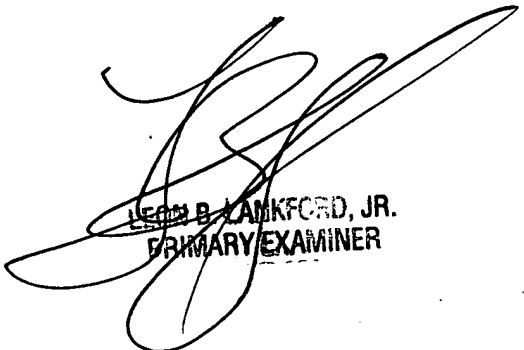
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford  
Examiner  
Art Unit 1651



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER